K123687

# Exactech® Optetrak Logic® Porous Femoral Component
# Traditional 510(k) – 510(k) Summary of Safety and Effectiveness

MAR 2 0 2013

**Sponsor:** Exactech® Inc.
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FDA Establishment Number 1038671

**Contact:** Patrick Hughes
Senior Regulatory Affairs Specialist

**Date:** March 18, 2013

**Trade or Proprietary or Model Name(s):**
Exactech® Optetrak Logic® Porous Femoral Component

**Common Name:**
Cemented Total Knee Prosthesis

**Classification Name:**
Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis

**Information on devices to which substantial equivalence is claimed:**

| 510(k) | Trade or Proprietary or Model Name | Manufacturer |
|---|---|---|
| K093360 | Optetrak Logic Total Knee System | Exactech, Inc |
| K111400 | Optetrak Logic CR Knee System | Exactech, Inc. |
| K121307 | Optetrak Logic CR Knee System Sizes 0 & 6 | Exactech, Inc. |
| K935726 | Optetrak Porous Coated Cruciate Retaining Femoral Component | Exactech, Inc. |
| K935773 | Exactech Posterior Stabilized Porous Femoral Component | Exactech, Inc. |

**Indications for Use:**
The OPTETRAK Comprehensive Knee Systems are indicated for use in skeletally mature individuals undergoing primary surgery for total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis and/or post-traumatic degenerative problems. They are also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

In the USA, the OPTETRAK Comprehensive Knee System is indicated for cemented use only.

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**Device Description:**
The proposed Optetrak Logic Porous Femoral Component devices represent modifications to existing Optetrak Logic Total Knee System (K093360) and Optetrak Logic CR Knee System femoral components (K111400 and K121307) used in total knee arthroplasty. The only difference between proposed Optetrak Logic Porous Femoral Components and predicate Optetrak Logic femoral components is the addition of a beaded, sintered cobalt-chrome coating to specific non-articulating areas of the subject devices, similar to the coating added to predicate Optetrak Porous Coated Cruciate Retaining Femoral Component devices cleared per 510(k) K935726 and predicate Exactech Posterior Stabilized Porous Femoral Component devices cleared per 510(k) K935773.

Both predicate and proposed devices share the following similarities:

- the same indications for use
- the same materials
- the same basic fundamental scientific technology
- the same device compatibility
- the same materials and processes used for packaging and sterilization

**Summary of Testing:**

| Evaluation | Results |
|---|---|
| Porosity, pore size, and coating thickness characterization per ASTM F1854-09 | • Mean porosity: 65.8%<br>• Mean pore size: 339.9 µm<br>• Mean tissue-interface coating thickness: 766.9 µm* |
| Shear strength evaluation per ASTM F1044-05 | • Mean shear strength: 40.6 MPa<br>• All test samples exceeded minimum 20 MPa |
| Tensile strength evaluation per ASTM F1147-05 | • Mean shear strength: 46.9 MPa<br>• All test samples exceeded minimum 20 MPa |
| Cadaver lab evaluation | • Surgeon determined prototype was implanted without difficulty |
| Shear fatigue testing per ASTM F1160-05 (n=5) | • Specimen 1.3 withstood 10 million load cycles at maximum shear stress of 22.5 MPa, specimen 1.4 failed after 2.4 million cycles, specimen 1.5 failed at adhesive/coating interface after 7.5 million cycles. Remaining specimens tested at higher stresses failed at adhesive/coating interfaces. |
| Abrasion resistance testing per ASTM F1978-12 | • No visible abrasion marks or particle shedding.<br>• Average material change after 100 abrasion cycles = 11.3 ± 13.4 mg |
| Chemical composition and material microstructure analysis | • Modified substrate of proposed device is equivalent to predicates per chemical composition, fine grain size, fine grain percentage, coarse grain size, grain size distribution, microstructure, and total average grain size. |

*Coating thickness measurement modified from standard as described in Section 003 – Standards Form 1854 and Section 010.

Per the Class II special controls guidance document *Knee Joint Patellofemorotibial and Femorotibial Metal/Polymer Porous-Coated Uncemented Prostheses; Guidance for Industry and FDA* issued January 16, 2003, FDA recommends that the porous coating have a volume porosity

between 30 to 70 percent, an average pore size between 100 to 1,000 microns, and a porous coating thickness of 500 to 1,500 microns.

**Substantial Equivalence Conclusion:**
Results of engineering studies referenced in this 510(k) submission demonstrate the proposed Optetrak Logic Porous Femoral Component devices are substantially equivalent to cited cleared predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 20, 2013

Exactech, Incorporated
% Mr. Patrick Hughes
Regulatory Affairs Specialist
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K123687
Trade/Device Name: Exactech® Optetrak Logic® Porous Femoral Component
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: February 25, 2013
Received: March 04, 2013

Dear Mr. Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Exactech® Optetrak Logic® Porous Femoral Component**
**Special 510(k) – Indications for Use**

**510(k) Number:** K123687

**Device Name: Exactech® Optetrak Logic® Porous Femoral Component**

**INDICATIONS**

The OPTETRAK Comprehensive Knee Systems are indicated for use in skeletally mature individuals undergoing primary surgery for total knee replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis and/or post-traumatic degenerative problems. They are also indicated for revision of failed previous reconstructions where sufficient bone stock and soft tissue integrity are present.

In the USA, the OPTETRAK Comprehensive Knee System is indicated for cemented use only.

**Prescription Use** ___X___ **and/or** **Over-The-Counter Use** _____
**(Part 21 CFR 801 Subpart D)** **(21 CFR 807 Subpart C)**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Casey L. Hanley, Ph.D.
Division of Orthopaedic Devices